

## § 500.90

(b) The regulatory method must reliably measure and confirm the identity of the marker residue in the target tissue at concentrations equal to and above  $R_m$ .

(c) FDA will publish in the FEDERAL REGISTER the complete regulatory method for measuring the marker residue in the target tissue in accordance with the provisions of sections 409(c)(3)(A), 512(d)(1)(H) and (i), and 721(b)(5)(B) of the act.

(Approved by the Office of Management and Budget under control number 0910-0228)

### § 500.90 Waiver of requirements.

In response to a petition or on the Commissioner's own initiative, the Commissioner may waive, in whole or in part, the requirements of this subpart except those provided under § 500.88. A petition for this waiver may be filed by any person who would be adversely affected by the application of the requirements to a particular compound. The petition shall explain and document why the requirements from which a waiver is requested are not reasonably applicable to the compound, and set forth clearly the reasons why the alternative procedures will provide the basis for concluding that approval of the compound satisfies the requirements of the anticancer provisions of the act. If the Commissioner determines that waiver of any of the requirements of this subpart is appropriate, the Commissioner will state the basis for that determination in the regulation approving marketing of the sponsored compound.

(Approved by the Office of Management and Budget under control number 0910-0228)

### § 500.92 Implementation.

(a) This subpart E applies to all new animal drug applications, food additive petitions, and color additive petitions concerning any compound intended for use in food-producing animals (including supplemental applications and amendments to petitions).

(b) This subpart E also applies in the following manner to compounds already approved:

(1) For those compounds that FDA determines may induce cancer when ingested by man or animals, i.e., suspect

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carcinogens, §§ 500.80(b), 500.82, and 500.90 apply.

(2) For those compounds that FDA determines have been shown to induce cancer when ingested by man or animals, §§ 500.82 through 500.90 apply.

## PART 501—ANIMAL FOOD LABELING

### Subpart A—General Provisions

Sec.

- 501.1 Principal display panel of package form animal food.
- 501.2 Information panel of package for animal food.
- 501.3 Identity labeling of animal food in package form.
- 501.4 Animal food; designation of ingredients.
- 501.5 Animal food; name and place of business of manufacturer, packer, or distributor.
- 501.8 Labeling of animal food with number of servings.
- 501.15 Animal food; prominence of required statements.
- 501.17 Animal food labeling warning statements.
- 501.18 Misbranding of animal food.

### Subpart B—Specific Animal Food Labeling Requirements

- 501.22 Animal foods; labeling of spices, flavorings, colorings, and chemical preservatives.

### Subparts C-E [Reserved]

### Subpart F—Exemptions From Animal Food Labeling Requirements

- 501.100 Animal food; exemptions from labeling.
- 501.103 Petitions requesting exemptions from or special requirements for label declaration of ingredients.
- 501.105 Declaration of net quantity of contents when exempt.
- 501.110 Animal feed labeling; collective names for feed ingredients.

AUTHORITY: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

SOURCE: 41 FR 38619, Sept. 10, 1976, unless otherwise noted.